CBER's database system, 90 percent of the conventional tissue banks are members of AATB (262 × 90 percent = 236), and 95 percent of eye tissue banks are members of EBAA (121 × 95 percent = 115). Therefore, we exclude burden for recordkeeping by these 351 establishments (236 + 115 = 351) from our estimate as we believe such recordkeeping is usual and customary business activity (5 CFR 1320.3(b)(2)). The recordkeeping burden, thus, is estimated for the remaining 32 establishments, which is 8.36 percent of all establishments (383 − 351 = 32, or 32/383 = 8.36 percent).

We assume that all current tissue establishments have developed written procedures in compliance with part 1270. Therefore, our estimated burden includes the general review and update of written procedures (an annual average of 24 hours), and the recording and justifying of any deviations from the written procedures under § 1270.31(a) and (b) (an annual average of 1 hour). The information collection burden for maintaining records concurrently with the performance of each significant screening and testing step and for retaining records for 10 years under § 1270.33(a), (f), and (h) include documenting the results and interpretation of all required infectious disease tests and results and the identity and relevant medical records of the donor required under § 1270.35(a) and (b). Therefore, the burden under these provisions is calculated together in table 1 of this document. The recordkeeping estimates for the number of total annual records and hours per record are based on information provided by industry and our experience with the information collection.

We estimate the burden of this information collection as follows:

TABLE 1—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

21 CFR part 1270; human tissue intended for transplantation	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
Subpart C—Procedures and Records					
1270.31(a), (b), (c), and (d) [2]	32	1	32	24	768
1270.31(a) and 1270.31(b) [3]	32	2	64	1	64
1270.33(a), (f), and (h), and 1270.35(a) and (b)	32	6,198.84	198,363	1.0	198,363
1270.35(c)	32	11,876.12	380,036	1.0	380,036
1270.35(d)	32	1,454.50	47,504	1.0	47,504
Total					626,735

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] Review and update of standard operating procedures (SOPs).
[3] Documentation of deviations from SOPs.

Based on a review of the information collection since our last OMB approval, we have made no adjustments to our burden estimate.

Dated: September 17, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–20669 Filed 9–23–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2019–P–2123]

Determination That ATROPINE SULFATE ANSYR PLASTIC SYRINGE (Atropine Sulfate Solution) Intravenous, Intramuscular, Subcutaneous, and Endotracheal, 0.5 Milligram/5 Milliliters (0.1 Milligram/Milliliter), Was Not Withdrawn From Sale for Reasons of Safety or Effectiveness

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) has determined that ATROPINE SULFATE ANSYR PLASTIC SYRINGE (atropine sulfate solution) intravenous, intramuscular, subcutaneous, and endotracheal, 0.5 milligram (mg)/5 milliliters (mL) (0.1 mg/mL), was not withdrawn from sale for reasons of safety or effectiveness. This determination will allow FDA to approve abbreviated new drug applications (ANDAs) for atropine sulfate solution intravenous, intramuscular, subcutaneous, and endotracheal, 0.5 mg/5 mL (0.1 mg/mL), if all other legal and regulatory requirements are met.

FOR FURTHER INFORMATION CONTACT: Carlarease Hunter, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6213, Silver Spring, MD 20993–0002, 301–796–3702, *Carlarease.Hunter@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98–417) (the 1984 amendments), which authorized the approval of duplicate versions of drug products under an ANDA procedure. ANDA applicants must, with certain exceptions, show that the drug for which they are seeking approval contains the same active ingredient in the same strength and dosage form as the ''listed drug,'' which is a version of the drug that was previously approved. ANDA applicants do not have to repeat the extensive clinical testing otherwise necessary to gain approval of a new drug application (NDA).

The 1984 amendments include what is now section 505(j)(7) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(7)), which requires FDA to publish a list of all approved drugs. FDA publishes this list as part of the ''Approved Drug Products With Therapeutic Equivalence Evaluations,'' which is known generally as the ''Orange Book.'' Under FDA regulations, drugs are removed from the list if the Agency withdraws or suspends approval of the drug's NDA or ANDA for reasons of safety or effectiveness or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (§ 314.162 (21 CFR 314.162)).

A person may petition the Agency to determine, or the Agency may determine on its own initiative, whether a listed drug was withdrawn from sale for reasons of safety or effectiveness.

This determination may be made at any time after the drug has been withdrawn from sale, but must be made prior to approving an ANDA that refers to the listed drug (§ 314.161 (21 CFR 314.161)). FDA may not approve an ANDA that does not refer to a listed drug.

ATROPINE SULFATE ANSYR PLASTIC SYRINGE (atropine sulfate solution) intravenous, intramuscular, subcutaneous, and endotracheal, 0.5 mg/5 mL (0.1 mg/mL), is the subject of NDA 021146, held by Hospira, Inc., and initially approved on July 9, 2001. ATROPINE SULFATE ANSYR PLASTIC SYRINGE (atropine sulfate solution) intravenous, intramuscular, subcutaneous, and endotracheal, 0.5 mg/5 mL (0.1 mg/mL), is indicated for temporary blockade of severe or life-threatening muscarinic effects (*e.g.,* as an antisialagogue, an antivagal agent, an antidote for organophosphorus or muscarinic mushroom poisoning, and to treat bradyasystolic cardiac arrest).

ATROPINE SULFATE ANSYR PLASTIC SYRINGE (atropine sulfate solution) intravenous, intramuscular, subcutaneous, and endotracheal, 0.5 mg/5 mL (0.1 mg/mL), has never been marketed. In previous instances (see *e.g.,* 72 FR 9763 (March 5, 2007) and 61 FR 25497 (May 21, 1996)), the Agency has determined that, for purposes of §§ 314.161 and 314.162, never marketing an approved drug product is equivalent to withdrawing the drug from sale.

Lachman Consultants submitted a citizen petition dated May 1, 2019 (Docket No. FDA–2019–P–2123), under 21 CFR 10.30, requesting that the Agency determine whether ATROPINE SULFATE ANSYR PLASTIC SYRINGE (atropine sulfate solution) intravenous, intramuscular, subcutaneous, and endotracheal, 0.5 mg/5 mL (0.1 mg/mL), was withdrawn from sale for reasons of safety or effectiveness.

After considering the citizen petition and reviewing Agency records and based on the information we have at this time, FDA has determined under § 314.161 that ATROPINE SULFATE ANSYR PLASTIC SYRINGE (atropine sulfate solution) intravenous, intramuscular, subcutaneous, and endotracheal, 0.5 mg/5 mL (0.1 mg/mL), was not withdrawn for reasons of safety or effectiveness. The petitioner has identified no data or other information suggesting that ATROPINE SULFATE ANSYR PLASTIC SYRINGE (atropine sulfate solution) intravenous, intramuscular, subcutaneous, and endotracheal, 0.5 mg/5 mL (0.1 mg/mL), was withdrawn for reasons of safety or effectiveness. We have carefully reviewed our files for records concerning the withdrawal of ATROPINE SULFATE ANSYR PLASTIC SYRINGE (atropine sulfate solution) intravenous, intramuscular, subcutaneous, and endotracheal, 0.5 mg/5 mL (0.1 mg/mL), from sale. We have also independently evaluated relevant literature and data for possible postmarketing adverse events. We have found no information that would indicate that this drug product was withdrawn from sale for reasons of safety or effectiveness.

Accordingly, the Agency will continue to list ATROPINE SULFATE ANSYR PLASTIC SYRINGE (atropine sulfate solution) intravenous, intramuscular, subcutaneous, and endotracheal, 0.5 mg/5 mL (0.1 mg/mL), in the ''Discontinued Drug Product List'' section of the Orange Book. The ''Discontinued Drug Product List'' delineates, among other items, drug products that have been discontinued from marketing for reasons other than safety or effectiveness. ANDAs that refer to ATROPINE SULFATE ANSYR PLASTIC SYRINGE (atropine sulfate solution) intravenous, intramuscular, subcutaneous, and endotracheal, 0.5 mg/5 mL (0.1 mg/mL), may be approved by the Agency as long as they meet all other legal and regulatory requirements for the approval of ANDAs. If FDA determines that labeling for this drug product should be revised to meet current standards, the Agency will advise ANDA applicants to submit such labeling.

Dated: September 17, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–20662 Filed 9–23–19; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–E–0267]

Determination of Regulatory Review Period for Purposes of Patent Extension; Med–El Electric and Acoustic Stimulation Hybrid Hearing Prosthesis System

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or the Agency) has determined the regulatory review period for MED–EL Electric and Acoustic Stimulation Hybrid Hearing Prosthesis System (MED–EL EAS) and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application to the Director of the U.S. Patent and Trademark Office (USPTO), Department of Commerce, for the extension of a patent which claims that medical device.

DATES: Anyone with knowledge that any of the dates as published (see the **SUPPLEMENTARY INFORMATION** section) are incorrect may submit either electronic or written comments and ask for a redetermination by November 25, 2019. Furthermore, any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period by March 23, 2020. See ''Petitions'' in the **SUPPLEMENTARY INFORMATION** section for more information.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before November 25, 2019. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of November 25, 2019. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the